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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2023-C-1487]

Filing of Color Additive Petition from Environmental Defense Fund, et al.; Request to Revoke Color Additive Listing for Use of Titanium Dioxide in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a color additive petition, submitted by Environmental Defense Fund, et al., proposing that FDA repeal the color additive regulation providing for the use of titanium dioxide in foods.

DATES: The color additive petition was filed on April 14, 2023. Either electronic or written comments must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comment, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper instructions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-C-1487 for "Filing of Color Additive Petition from Environmental Defense Fund, et al.; Request To Revoke Color Additive Listing for Use of Titanium Dioxide in Food." Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Paulette M. Gaynor, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1192.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 3C0325), submitted by Environmental Defense Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, and Environmental Working Group, c/o Tom Neltner, 1875 Connecticut Ave. NW, Washington, DC 20009. The petition proposes that we repeal the color additive regulation for titanium dioxide in § 73.575 (21 CFR 73.575), which permits the use of titanium dioxide in foods.

II. Request to Repeal section 73.575

In accordance with the procedure in section 721(d) of the FD&C Act for issuance, amendment, or repeal of regulations, the petition asks us to repeal section 73.575 to no longer provide for the use of titanium dioxide in foods. The petitioners assert that the intended use of this color additive no longer meets the safety standard under 21 CFR 70.3(i), and cite, as evidence, an opinion by the European Food Safety Authority (EFSA) entitled "Safety assessment of titanium dioxide (E171) as a food additive" that was published in May 2021 (we are using EFSA's title for this document, rather than the one cited by the petitioners), and other publications.

We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify repealing section 73.575 to no longer provide for the safe use of titanium dioxide in foods, we will publish our decision in the *Federal Register* in accordance with 21 CFR 71.20.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact

statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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